UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PZIFER INC., ET AL.,	**1:08-cv-02018-LAK**
Plaintiffs,	
-against-	**DEFENDANT'S MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION TO DISMISS DEFENDANT'S COUNTERCLAIMS**
MATHEW I. GELFAND,	
Defendant.	

Defendant, Mathew I. Gelfand ("Gelfand"), by and through his undersigned counsel, hereby respectfully submits his opposition to Plaintiffs' motion to dismiss his Counterclaims. For the reasons set forth below, Plaintiffs' motion should be denied.

I. INTRODUCTION

Plaintiffs have moved to dismiss Gelfand's Counterclaims in part. Plaintiffs do not seek to dismiss Gelfand's Second Claim for Relief against Defendant Pfizer, Inc. ("Pfizer"), for damages and injunctive relief arising out of Pfizer's active inducement of infringement of Gelfand's '688 Patent, as prohibited by 35 U.S.C. § 271(b).

Instead, Plaintiffs argue as follows:

(a) that Gelfand's First Claim for Relief against all Defendants for direct infringement under 35 U.S.C. § 271(a) by the unauthorized sale of Lipitor® and Caduet® should be dismissed because Gelfand does not sufficiently allege that Defendants have "performed" the method claimed in Gelfand's '688 Patent;

(b) that Defendants Robert Jarvik ("Jarvik") and Jarvik Heart, Inc. ("JHI"), only should be dismissed from Gelfand's Second Claim for Relief seeking damages and injunctive relief for active inducement of infringement of Gelfand's '688

Patent, prohibited by 35 U.S.C. § 271(b), because Gelfand does not sufficiently allege that Jarvik and JHI had knowledge of the '688 Patent during the time that Jarvik and JHI were promoting Pfizer's product, Lipitor®;

(c) that Gelfand's Third Claim for Relief, which alleges a violation of 35 U.S.C. § 271(e)(2) against Pfizer only, should be dismissed because Gelfand does not allege that any of several "predicates to infringement"[1] under that statute have occurred;

(d) that Gelfand's Fourth Claim for Relief, which alleges a violation by Pfizer only of 35 U.S.C. § 271(a) through Pfizer's unauthorized manufacture or "making" of Lipitor® and Caduet® should be dismissed because Gelfand does not sufficiently allege that Defendants have "performed" the method claimed in Gelfand's '688 Patent; and

(e) that all claims alleged against JHI should be dismissed because Gelfand does not allege "any affirmative act by JHI that cold directly or indirectly infringe any claim of the '688 patent."[2]

In support of the dismissal of the claims as described above, Defendants rely on materials and assertions that are outside of Gelfand's Counterclaims (although the contract between Jarvik's two-year contract with Pfizer for the promotion of Lipitor® is fairly inferable from the counterclaims).

Plaintiffs overstate the quality of factual allegations that are necessary to withstand their motion to dismiss in this case, which arises under the United States patent laws, 35 U.S.C. Whatever standard of pleading may apply to allegations of securities fraud (at issue in *ATSI*

[1] Memorandum of Law in Support of Plaintiffs' Motion to Dismiss, page 23.

[2] *Id.*, page 17.

Comm, Inc. v. Shaar Fund, Ltd., 493 F.3d 87 (2d Cir. 2007), or to allegations overcoming qualified immunity in a civil rights dispute (at issue in *Iqbal v. Hasty*, 490 F.3d 143 (2d Cir. 2007),[3] the pleading standard for a patent case remains as it was pre-*Twombley*:

> Federal Rule 8(a)(2) requires only "a short and plain statement of the claim showing that the pleader is entitled to relief." Specific facts are not necessary; the statement need only "give the defendant fair notice of what the . . . claim is and grounds upon which it rests." In addition, when ruling on a defendant's motion to dismiss, a judge must accept as true all of the factual allegations contained in the complaint.

Erickson v. Pardus, 127 S.Ct. 2197, 2198 (U.S. 2007) (quoting *Twombley* and other authority) (citations omitted); *McZeal v. Sprint Nextel Corp.*, 501 F.3d 1354, 1356-57 (Fed. Cir. 2007) (citing *Twombley*) (holding that Fed. R. Civ. P Form 16 (2006), which provides a sample patent infringement complaint, along with *Conley v. Gibson*, 355 U.S. 41, 47 (U.S. 1957) ("stating that '[the] illustrative forms appended to the Rules plainly demonstrate [the pleading requirements]'") continue to guide the pleading requirements for patent claims. Nowhere in their motion do Plaintiffs argue that Gelfand's counterclaim fail to put them on sufficient notice of "'what the claim is and grounds upon which it rests.'" *Id.* To the contrary, Gelfand's factual allegations are well-pleaded, and all reasonable inferences therefrom are to be drawn in his favor upon review of Plaintiffs' motion to dismiss his counterclaims.

II. ARGUMENT

Each of Plaintiffs' arguments on Gelfand's claims is taken in turn below.

A. Gelfand's First Claim for Relief: Gelfand need only plead Defendants' sale of Gelfand's method to plead a claim of direct infringement under 35 U.S.C. § 271(a). The cases upon which Plaintiffs rely in an attempt to establish that Gelfand has not alleged a violation

[3] Plaintiffs rely on *Iqbal* for the proposition that the Second Circuit has refused to limit to antitrust pleadings the Supreme Court's "plausibility" standard as stated in *Bell Atlantic Corp. v. Twombley*, 127 S.Ct. 1955 (U.S. 2007). But *Iqbal*'s authority is in question now, as the Supreme Court has granted the Attorney General's petition for a writ of *certiorari* in that case. *Ashcroft v. Iqbal*, 2008 U.S. LEXIS 4906 (U.S. June 16, 2008).

of direct infringement under 35 U.S.C. § 271(a) are all inapposite. Section 271(a) provides simply that "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." Gelfand has alleged that Defendants have sold and offered to sell his patented method invention, the '688 patent, in connection with their promotion and sale of Lipitor® and Caduet®. With one exception, the cases upon which Plaintiffs rely involve allegations that the mere sale of a thing (apparatus or device) merely implied the violation of a patented method. But that is precisely *not* what Gelfand has alleged in his counterclaims and, specifically, in his First Claim for Relief. To the contrary, Gelfand has explicitly alleged that the actual *promotion* of Lipitor® and Caduet® – the sale and offering for sale of these items – infringed and continue to infringe his patented method. The exception is Plaintiffs' reliance on *Catapano v. Wyeth Ayerst Pharm., Inc.*, 88 F. Supp.2d 27, 23-30 (E.D.N.Y. 2000), for the proposition that the pleader's failure to allege the sale of a patented method is fatal to a claim for direct infringement. Here, Gelfand has alleged what was missing in *Catapano*: the infringer's sale and offering for sale of a method patented by someone other than the salesmen.

B. Gelfand's Second Claim for Relief against Jarvik and JHI: What Jarvik and JHI knew, and when they knew it, are questions of material fact. Gelfand has alleged a contractual relationship between Jarvik and Pfizer that, among other things, required the sharing of information regarding the sale of Lipitor®. In this regard, what Jarvik knew about Gelfand's '688 patent prior the commencement of this action is a genuine issue of material fact. To impose on Gelfand a more onerous requirement at the pleading stage than he would face upon summary judgment would be turn Rule 8 of the Federal Rules of Civil Procedure on its head.

C. Gelfand's Third Claim for Relief: Gelfand need only plead that Pfizer's NDA and SNDA are "described" in section 505(b)(2) of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(2). Section 271(e)(2)(A) is clear: it establishes that "it shall be an act of infringement to submit . . . an application . . . *described* in section 505(b)(2)" of the federal Food, Drug, and Cosmetic Act (emphasis added). An application described in Section 505(b)(2) is any application for:

> a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

21 U.S.C. § 355(b)(2). Plaintiffs argue that, because Gelfand has alleged that Pfizer filed an NDA and an SNDA, Gelfand cannot prove any facts that would satisfy the requirements of 35 U.S.C. § 271(e)(2)(A). That question is to be tested after discovery, not at the pleading stage.[4] To adopt Plaintiffs' view of the facts that Pfizer's NDA and its SNDA relied upon investigations conducted by or for Pfizer or, if not, upon investigations for which Pfizer has "obtained a right or reference or use" is to allow Plaintiffs to attempt to prove facts upon their motion to dismiss, which instead must accept as true all well-pleaded allegations in Gelfand's complaint and reasonable inferences therefrom.

D. Gelfand's Fourth Claim for Relief: Gelfand need only plead that Pfizer manufactured Lipitor® and Caduet® for an infringing purpose. Gelfand has alleged that during the period that Pfizer has promoted Lipitor® and Caduet® for an infringing purpose, Pfizer has manufactured these two compounds for an infringing purpose. Plaintiffs rely on the

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[4] Plaintiffs argue that congressional intent in the enactment of 35 U.S.C. §271(e) should control the application of that statute. But that is not the law, and Plaintiffs offer no reason, much less a compelling reason, to invite this Court to depart from the plain language of the statute. *See Duncan v. Walker*, 533 U.S. 167, 174 (U.S. 2001) ("Our task is to construe what Congress has enacted. We begin, as always, with the language of the statute.").

very authority that undermines their proposition. In *Hilgraeve Corp. v. Symantec Corp.*, 265 F.3d 1336, 1343 (Fed. Cir. 2001), the Federal Circuit restated the rule that the manufacturer of a device may be liable for infringement even if his device is capable of non-infringing uses. In effect, the manufacture of Lipitor® and Caduet® is not to be viewed in isolation from the purposes for which Pfizer, in whole or in part, sold or offered to sell them.

E. Gelfand's claims against JHI do not require any allegation of an affirmative act by JHI alone. Gelfand has alleged that Jarvik, for his own benefit and for the benefit of JHI, infringed Gelfand's '688 patent directly and indirectly. Gelfand has alleged facts that, if true, demonstrate that, for purposes of the sale and offering for sale of Lipitor®, JHI and Jarvik are to be treated as alter-egos and inextricable. *See, e.g., Systems Divison, Inc. v. Teknek Electronics, Ltd.*, 253 Fed. Appx. 31, 34-35 (Fed. Cir. 2007) (recognizing alter-ego theory in a patent infringement context).

WHEREFORE, Defendant Gelfand respectfully requests that the Court deny Plaintiffs' motion to dismiss.

Dated: June 19, 2008
Bethesda, Maryland

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that, on this 19th day of June 2008, I caused a copy of the foregoing **DEFENDANT'S MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION TO DISMISS DEFENDANT'S COUNTERCLAIMS** to be delivered via ECF filing and by United States Mail, postage prepaid, to:

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